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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,435,989

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No.5,435,989 , which claims the method of use of the human drug product DaunoXome® (daunorubicin citrate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 259 days. U.S. Patent No. 5,435,989 has an original expiration date of May 28, 2008, subject to the provisions of 35 U.S.C. § 41(b). Accordingly, extension of the patent for 259 days will result in an extended expiration date of February 11, 2009.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to the requirement for an election may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration and if the above-identified patent is elected, the Commissioner will issue a certificate of extension, under seal, for a period of 259 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of March 21, 1997 (62 Fed. Reg. 13,651). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (1,629 - 1,629) + 1,142 - 883
= 259 days

Since the regulatory review period began September 8, 1988, before the patent issued, July 25, 1995, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. 35 U.S.C. § 156(c). The testing phase of an approved product is defined as the period beginning on the date that an exemption under subsection 505(i) of the Federal Food Drug and Cosmetic Act became effective for the approved product, September 8, 1988, and ending on the date an application for the approved product was initially submitted under section 507, February 22, 1993. Since both of these dates were before the issue date of the patent, none of the testing phase has been considered. The approval phase of a product begins on the date the application for the approved product was initially submitted. For DaunoXome®, this date was February 22, 1993, which was before the issue date of the patent, July 25, 1995. Accordingly, since from February 22, 1993 to July 25, 1995 is 883 days; this period is subtracted from the number of days occurring in the approval phase

according to the FDA determination of the length of the regulatory review period: 1,142 - 883 = 259 days. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the 14 year exception of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156(g)(6) operate to reduce the period of extension determined above.

It is noted that applicant has also filed applications for patent term extension of U.S. Patent Nos. 5,019,369 and 5,441,745 based upon the regulatory review of the product DaunoXome®. No more than one patent may be extended based upon a regulatory review period of a product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. Applicant is hereby **REQUIRED TO ELECT** a single patent for extension. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be dismissed. (The application for patent term extension for U.S. Patent No. 5,019,369 will be granted.) Accordingly, if the above-identified patent is elected, the Commissioner will issue a certificate of extension, under seal, for a period of 259 days.

Upon issuance of any certificate of extension in the above-identified patent, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,435,989
Granted	:	July 25, 1995
Original Expiration Date	:	May 28, 2008
Applicant	:	Cary A. Presant et al.
Owner of Record	:	NeXstar Pharmaceuticals, Inc.
Title	:	Method of Targeting a Specific Location in a Body
Classification	:	424/1.21
Product Trade Name	:	DaunoXome® (daunorubicin citrate)
Term Extended	:	259 days
Expiration Date of Extension	:	February 11, 2009

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents Box Patent Ext. Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
By hand:	One Crystal Park, Suite 520 2011 Crystal Drive Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
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RE: DaunoXome®
FDA Docket No.: 96E-0289